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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,531	11/28/2000	Ari Derowe	088/01925	5181

26418 7590 09/15/2003

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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N, K

Office Action Summary	Application N .		Applicant(s)	
	09/701,531		DEROWE ET AL.	
	Examiner		Art Unit	
	(Jackie) Tan-Uyen T. Ho		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-135, 143-158 and 176-218 is/are pending in the application.
- 4a) Of the above claim(s) 1-135, 176-199 and 206-218 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 143-158 and 200-205 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5-10, 12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group II (claims 143-158 and 205) in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the distal portion of the outer tube has an outer diameter which is substantially the same as an outer diameter of the punch element" as claimed claim 143 and a punch element having a depression distal from the tip "wherein the punch element is radially expandable from a first small diameter to a second working diameter" as claimed in claim 154, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 143-158 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the punch element fits snugly in the distal portion of an outer tube, does not reasonably provide enablement for the outer diameters of the distal portion and punch element are the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. If the outer diameters of the distal portion and punch element are the same then the punch element cannot fit in the distal portion.

6. Claims 143-158 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose the outer diameters of the distal portion and punch element are the same.

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7. Claims 154 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose a punch element having a depression distal from the tip wherein the punch element is radially expandable from a first small diameter to a second, working diameter.

8. Claim 154 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a punch element having a depression distal to its tip, does not reasonably provide enablement for the punch element being radially expandable from first, small diameter to a second, working diameter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 151-153 and 155 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 151-153 and 155 recite the limitation "said distal end." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 143-149, 151, 153, 200-205 are rejected under 35 U.S.C. 102(e) as being anticipated by Gifford, III et al. (5,695,504).

In regard to claim 143, Gifford, III et al. disclose an apparatus including an outer tube (137) having a distal portion with a lip (138), a punch element (136) with a shaft tip for penetrating a blood vessel and a depression (at the neck 135, figs. 4-5D) distal from the tip wherein the lip can sever blood vessel tissue contained in the depression from tissue outside the depression (col. 17, lines 1-38).

In regard to claim 144, the depression is distanced from the tip so that the distance is at least the thickness of the blood vessel (figs. 4-5D).

In regard to claim 145, the apparatus is flexible enough to be provided through a blood vessel in which a hole is to be punched.

In regard to claim 146, the apparatus includes a handle (133).

In regard to claim 147, the apparatus includes means for advancing the outer tube relative to the handle and relative to the punch element (col. 17, lines 1-38).

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In regard to claim 148, the apparatus includes means for retracting the punch element relative to the handle and relative to the outer tube (figs. 4-5E).

In regard to claim 149, the apparatus includes means (figs. 5F-5G) for advancing a graft into the hole formed by the punch element.

In regard to claim 151, the apparatus includes a stop (101) for preventing entry of the apparatus into the hole.

In regard to claim 153, the apparatus includes a stop (129,130) for preventing advance of the punch element relative to the apparatus, beyond a pre-defined distance.

In regard to claims 200-205, Gifford, III et al. disclose the method of punching a hole in a blood vessel including the steps as claimed (figs. 4-5F).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 152, 156, 157 and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. (5,695,504) in view of Yang et al. (5,989,287). Gifford, III et al. disclose an apparatus for making an anastomotic connection. Although, Gifford, III et al. do not disclose the apparatus configured to punch an oblique hole, Yang et al. teach and suggest that depending upon the type, location, size and shape of the artery or aorta, an anastomotic connection would be better with an oblique shape in

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certain case (col. 5, line 21 to col. 7, line 30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Gifford, III et al.'s apparatus by having outer tube and the puncher element of the apparatus in an oblique configuration to punch an oblique hole in order to make a best anastomosis connection for certain blood vessels.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
September 12, 2003